FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website and at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before January 16, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled on February 6, 2024, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 5, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 8, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*).

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25459 Filed 11–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3926]

Request for Nominations for Voting Members on Public Advisory Panels or Committees; Device Good Manufacturing Practice Advisory Committee and the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. This annual notice is also in accordance with the 21st Century Cures Act, which requires the Secretary of Health and Human Services (the Secretary) to provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before January 16, 2024, will be given first consideration for membership on the DGMPAC and Panels of the MDAC. Nominations received after January 16, 2024, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, contact the following persons listed in table 1:*

TABLE 1—PRIMARY CONTACT AND PANEL

Primary contact person	Committee or panel
Joannie Adams-White, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5561, Silver Spring, MD 20993, 301–796–5421, *Joannie.Adams-White@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel.
James P. Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993, 301–796–6313, *James.Swink@fda.hhs.gov*.	Circulatory System Devices Panel, Ophthalmic Devices Panel.
Akinola Awojope, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 301–636–0512, *Akinola.Awojope@fda.hhs.gov*.	Dental Products Panel, Neurological Devices Panel, Obstetrics and Gynecology Devices Panel, Orthopaedic and Rehabilitation Devices Panel.

TABLE 1—PRIMARY CONTACT AND PANEL—Continued

Primary contact person	Committee or panel
Jarrod Collier, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993, 240–672–5763, *Jarrod.Collier@fda.hhs.gov*.	DGMPAC, General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Molecular and Clinical Genetics Panel.
Candace Nalls, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993, 301–636–0510, *Candace.Nalls@fda.hhs.gov*.	Anesthesiology and Respiratory Therapy Devices Panel; Ear, Nose, and Throat Devices Panel; Gastroenterology and Urology Devices Panel.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for vacancies listed in table 2:

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED

Expertise needed	Vacancies	Approximate date needed
Device Good Manufacturing Practice Advisory Committee—Experts in medical device quality management system requirements/current good manufacturing practices, with experience in both part 820 (21 CFR part 820) and International Organization for Standardization (ISO) 13485, are needed to provide cross-cutting scientific or clinical expertise concerning the particular issue in dispute. Vacancies include representatives of the interests of the general public and government.	1 2	Immediately. June 1, 2024.
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee—Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, sleep medicine, pharmacology, physiology, or the effects and complications of anesthesia. FDA is also seeking applicants with pediatric expertise in these areas.	1	December 1, 2024.
Circulatory System Devices Panel of the Medical Devices Advisory Committee—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	3	July 1, 2024.
Dental Products Panel of the Medical Devices Advisory Committee—Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, oral and maxillofacial surgery, endodontics, periodontology, tissue engineering, snoring/sleep therapy, and dental anatomy.	7	Immediately.
Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee—Otologists, neurotologists, and audiologists.	7	Immediately.
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee—Gastroenterologists, urologists, and nephrologists.	2	January 1, 2024.
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, human factors experts, or microbiologists/infection control practitioners or experts.	1 2	Immediately. January 1, 2024.
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee—Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers, molecular oncology, cancer screening, cancer risk, digital pathology, whole slide imaging; devices utilizing artificial intelligence/machine learning.	4	Immediately.
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—Experts with cross-cutting scientific, clinical, analytical or mediation skills.	1 1	Immediately. October 1, 2024.
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee—Experts in human genetics, molecular diagnostics, and in the clinical management of patients with genetic disorders, and (*e.g.,* pediatricians, obstetricians, neonatologists). Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, bioinformatics, computational genetics/genomics, variant classification, cancer genetics/genomics, molecular oncology, radiation biology, and clinical molecular genetics testing, (*e.g.,* sequencing, whole exome sequencing, whole genome sequencing, non-invasive prenatal testing, cancer screening, circulating cell free/circulating tumor nucleic acid testing, digital polymerase chain reaction, genotyping, array comparative genomic hybridization, etc.). Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2	Immediately.
Neurological Devices Panel of the Medical Devices Advisory Committee—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	2 2	Immediately. December 1, 2023.

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED—Continued

Expertise needed	Vacancies	Approximate date needed
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee—Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	2	February 1, 2024.
Ophthalmic Devices Panel of the Medical Devices Advisory Committee—Ophthalmologists with expertise in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; and ophthalmic professionals with expertise in clinical trial design, quality of life assessment, electrophysiology, low vision rehabilitation, and biostatistics.	3	November 1, 2024.
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee—Orthopaedic surgeons (joint, spine, trauma, reconstruction, sports medicine, hand, foot and ankle, and pediatric orthopaedic surgeons); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, and musculoskeletal engineering; radiologists specializing in musculoskeletal imaging and analyses and biostatisticians.	1 2	Immediately. September 1, 2024.

I. General Description of the Committees Duties

A. DGMPAC

The DGMPAC reviews regulations proposed for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage and installation of devices, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding the feasibility and reasonableness of those proposed regulations. The DGMPAC also advises the Commissioner on any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations that is referred to the committee.

B. Panels of MDAC

The MDAC reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in many activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, performs the following duties: (1) advises the Commissioner regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Voting Members

A. DGMPAC

The DGMPAC consists of a core of nine members including the Chair. Members and the Chair are selected by the Secretary. Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: quality assurance concerning the design, manufacture, and use of medical devices in accordance with part 820 and/or ISO 13485. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the DGMPAC's work. Three of the members shall be officers or employees of any State or local government or of the Federal Government; two shall be representative of the interests of the device manufacturing industry; two shall be representatives of the interests of physicians and other health professionals; and two shall be representatives of the interests of the general public. FDA is publishing a separate document announcing the Request for Nominations Notification for Non-Voting Representatives of the interests of the device manufacturing industry. Almost all non-Federal members of this committee serve as Special Government Employees. Members are invited to serve for overlapping terms of 4 years. The current needs for the DGMPAC are listed in table 2.

B. Panels of the MDAC

The MDAC with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government

Employees. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Nonvoting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The current needs for each panel are listed in table 2. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committees or panel(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25367 Filed 11–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; Final Guidance for Industry and Food and Drug Administration Staff; and Select Updates for the 506J Guidance: 506J Device List and Additional Notifications; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the final guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' and the draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires manufacturers to notify FDA of a permanent discontinuance or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States during or in advance of a public health emergency (PHE). This final guidance is intended to assist manufacturers in providing timely, informative notifications about changes in the production of certain medical device products that will help prevent or mitigate shortages of such devices. FDA is concurrently issuing a draft guidance to propose select updates to the final guidance ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' This draft guidance proposes a list of device product codes for which a manufacturer of such devices is required to notify FDA in accordance with the FD&C Act (hereafter referred to as the ''506J Device List'') and clarifies that manufacturers may submit voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 15, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0053 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' or ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov*